

### **REMARKS**

Reconsideration of this application is respectfully requested.

Claims 27-47 were previously pending in the application. Claims 27, 46 and 47 have been amended; no claims have been added or cancelled by this Amendment. Accordingly, claims 27-47 are presented for further examination.

In a sincere effort to define their invention more clearly, Applicants have amended each of claims 27, 46 and 47. As amended hereinabove, the preamble of claim 27 recites "[a] composition which comprises a transparent non-porous or translucent non-porous system . . ." With the foregoing insertion which adopts the Examiner's position, the language in the claim clearly indicates that the "non-porous" limitation is connected to the transparent as well as the translucent limitations. Likewise, in the case of the apparatus claim 46, the solution in 1) is now defined as "containing means comprising a transparent non-porous or translucent non-porous device." In claim 47, the first (i) and second (ii) elements have both been amended to clarify the distinction between a nucleic acid, i.e., an oligonucleotide or polynucleotide strand, and a [nucleic acid] sequence, the latter (sequence) being a characteristic of the former (nucleic acid).

In addition to the foregoing changes, Applicants have also amended claims 27 and 47 to recite that the "signalling moiety is capable of generating a soluble signal." It is believed that this recitation conforms with the issued claims in U.S. Patent No. 4,994,373, which was based upon U.S. Patent Application Serial No. 07/385,986 (filed on July 20, 1989), the grandparent to the instant application.

Before addressing the substantive rejections raised in the October 21, 1994 Office Action, Applicants' undersigned attorney respectfully points out that the title of the invention was previously amended in the Preliminary Amendment that accompanied the continuation request filed on October 28, 1992. As requested in the Preliminary Amendment (page 2), the title should read "Composition and Kit Employing Chemically Labelled Polynucleotide Probes." This title is believed to be descriptive of the instantly claimed invention, and has been used in the caption of this

Amendment as well as the accompanying formal papers (transmittal, extension request).

**The Rejection Under 35 U.S.C. §112, First Paragraph**

Claims 27-47 stand rejected for indefiniteness under 35 U.S.C. §112, first paragraph. In the Office Action (page 2), the Examiner stated that "[i]n claim 27, line 2, and those dependent therefrom, it is unclear whether the 'non-porous' limitation is meant to be connected both to the transparent as well as the translucent limitations. Claim 46, part 1), also contains this unclarity." The Examiner also noted that "the use of 'sequence' [in claim 47] as if it were a composition is vague and indefinite in that a 'sequence' is a characteristic of a nucleic acid but not in itself a composition."

The Examiner's position is well taken. As indicated in the opening remarks to this Amendment, the claims in question (27, 46 and 47) have been amended to clarify or obviate all of the points in the indefiniteness rejection.

In view of the above amendments to the claims, Applicants respectfully request reconsideration and withdrawal of the rejection under §112, first paragraph.

**The Rejection Under 35 U.S.C. §101**

Claims 27-45 stand rejected under 35 U.S.C. §101 for lack of utility. In the Office Action (page 3), the Examiner stated that "there is no instantly disclosed utility for a double stranded containing composition. It is acknowledged that probes that are single stranded have utility as probes but after a double stranded form has been produced as cited in claims 27-45, it no longer has a utility such as for detection.

This ground of rejection is respectfully traversed.

In response, Applicants respectfully point out that the double-stranded oligonucleotide or polynucleotide recited in the instant claims does indeed possess utility in that the actual detection of the polynucleotide sequence of interest may not have been carried out at the point where the double-stranded form has been produced. In effect, in the

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instant invention, Applicants are claiming an intermediate product which can be detected. The changes to the signalling moiety in claims 27 and 47, which conform to the issued claims in U.S. Patent No. 4,994,373, reflect this aspect. It is further respectfully submitted that such a "double stranded form" as set forth in the instant claims, pass the statutory strictures for utility, irrespective of whether detection has been carried out.

Reconsideration and withdrawal of the rejection under §101 is respectfully requested in view of the foregoing remarks.

**The Rejection For Double Patenting (Obviousness Type)**

Claims 27-47 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-19 of U.S. Patent No. 4,994,373. As stated in the Office Action (page 3), "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because both are directed to either compositions, kits, or apparatus containing immobilized polynucleotides directed to soluble signal generation connected with hybridization."

In response, Applicants are submitting herewith a Terminal (Statutory) Disclaimer attached hereto as Exhibit 1. The Terminal (Statutory) Disclaimer (Exhibit 1) has been signed by Barry W. Weiner, as Executive Vice President on behalf of the assignee of record, Enzo Diagnostics, Inc. As noted under Mr. Weiner's signature, he was/is duly authorized to sign on behalf of the assignee. The Terminal (Statutory) Disclaimer (Exhibit 1) includes a completed, signed Certificate under 37 C.F.R. §3.73(b) as set forth in the July 6, 1992 Federal Register (Vol. 52, No. 129, 29634-29648) and in the July 28, 1992 Official Gazette.

According to page 2 (first full paragraph) in the Terminal (Statutory) Disclaimer (Exhibit 1), Enzo Diagnostics, Inc. disclaims the terminal part of any patent granted on the subject application which would extend beyond the expiration date of U.S. Patent No. 4,994,373, also assigned to and owned by Enzo Diagnostics, Inc. and agrees that any patent so granted shall be enforceable only for and during such period that the legal title to the patent shall be the same as the legal title to U.S. Patent No. 4,994,373.

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Serial No. 07/967,646  
Filed: October 28, 1992  
Page 6 (Amendment Under 37 C.F.R. §1.115 - April 22, 1994)

As noted on pages 2 and 3 in the Terminal (Statutory) Disclaimer (Exhibit 1), The Patent and Trademark Office is authorized to charge Deposit Account 05-1135 for the requisite fee of \$110.00 (and any additional fees) in connection with the filing of the document.

In view of the Terminal (Statutory) Disclaimer (Exhibit 1) submitted herewith, Applicant respectfully requests that the obviousness-type double patent rejection be reconsidered and withdrawn, thereby placing all of the claims (27-47) in condition for allowance. An early indication as to their allowability is earnestly solicited.

#### **Submission of Art-Related Documents**

Applicants' attorney intends to file shortly an Information Disclosure Statement Under 37 C.F.R. §§1.56 & 1.99 in order to provide the Examiner with all art-related documents.

In order to expedite review, Applicants' attorney is filing this Amendment and the attached exhibits by Express Mail.

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**SUMMARY AND CONCLUSIONS**

Claims 27-47 are presented for further examination. Claims 27, 46 and 47 have been amended; no other claims have been amended, added or cancelled by this Amendment.

This Amendment is accompanied by a Request For a Three-Month Extension of Time and authorization for the \$840.00 fee therefor. The Patent and Trademark Office is authorized to charge Deposit Account 05-1135 for any other fees in connection with this Amendment or the accompanying Terminal (Statutory) Disclaimer [Exhibit 1], and to credit any overpayment thereto.

In view of the above discussion of the issues and submitted exhibits, Applicants respectfully submit that each of claims 27-47 is in condition for allowance. A favorable and speedy reconsideration of their rejection is requested. If any of these claims are found not to be in condition for allowance for any reason, the Examiner is respectfully requested to telephone the undersigned at (212) 856-0876 to discuss the subject application.

Respectfully submitted,



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